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C3C
B5A
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(54) Vascular prosthesis

(57) Small diameter vascular prostheses with substantially uniform microporous walls are made by drawing a polymer solution by vacuum into a hollow rod so as to coat the interior surface of the rod and then contacting the polymer solution coating with a fluid coagulant. The polymer is suitably a polyurethane.

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The drawing(s) originally filed was (were) informal and the print here reproduced is taken from a later filed formal copy.

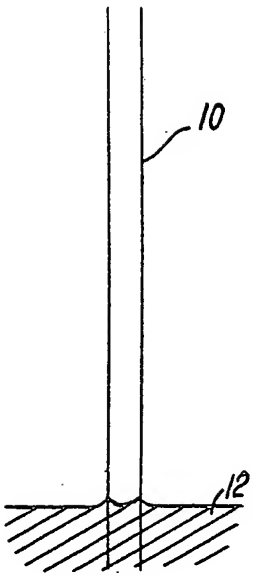

FIG. 1

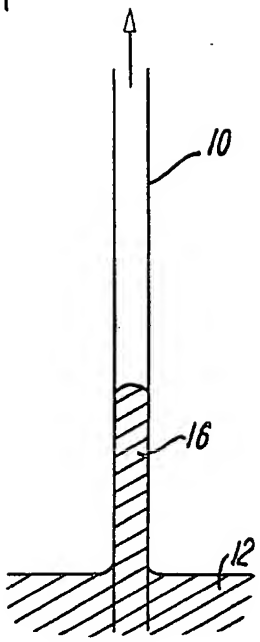

FIG. 2

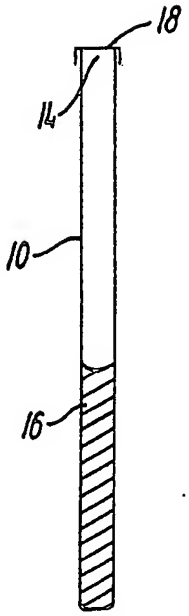

FIG. 3

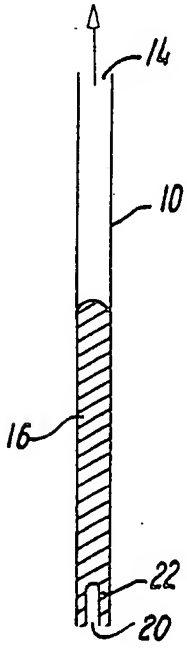

FIG. 4

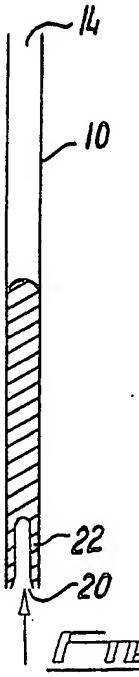

FIG. 5

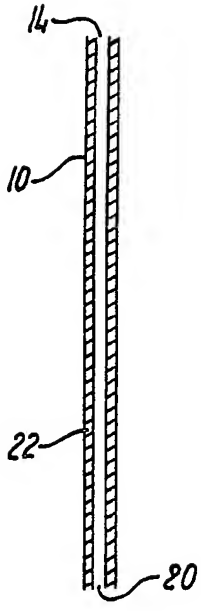

FIG. 6

VASCULAR PROSTHESIS

This invention relates to microporous material and in particular microporous tubes.

Microporous polymer tubes which may be used as artificial body organs, e.g. vascular prostheses, are well known. For example U.S. Patent Specification No.4173689 describes a process whereby a polymer which is blood and body-tissue compatible is fabricated into a vascular prosthesis by dipping a cylindrical mandrel into a solution of the polymer, withdrawing the mandrel, and developing the polymer structure by immersing the coated mandrel in a coagulation bath. Repeated dipping/coagulation cycles are usually necessary to build up the required wall thickness by this method.

In another process, disclosed in U.S. Patent Specification No.4552707 vascular prostheses are produced by continuously spraying a rotating mandrel held in an electrostatic field with polymer solution from a traversing syringe. The electrostatic field causes the polymer to form discrete fibrils, which, after deposition on the mandrel and evaporation of the solvent, yield a porous tube with the required mechanical properties for a vascular replacement.

These processes, particularly the former, are adequate for production of some prostheses. However, small diameter prostheses must have the mechanical properties similar to those of natural tissue in order to withstand the repeated surge of fluid therethrough. It has been found difficult to obtain products which will meet those requirements from the above-mentioned processes.

In an attempt to deal with that problem we developed a process which is disclosed in our British Patent No.2102821 in which the desired wall thickness is built up in a single operation by passing polymer solution through the annulus formed when a solid, inert mandrel is concentrically held in a mould of appropriately greater diameter. The wall of the mould contains a releasable fluid, which is miscible with the solvent, but is a non-solvent for the polymer. This non-solvent diffuses into the solution as the latter flows through the annulus, thus coagulating the polymer.

Even this process has not proved entirely satisfactory and possibly because like the earlier processes, coagulation is initiated at the outer surface of the polymer tube.

The invention has been made with these problems in mind.

According to the invention there is provided a process for producing a cellular or microporous polymer product comprising drawing a polymer solution into a hollow body to form a lining of said polymer solution over at least a part of the inner surface of the body and contacting the said lining with a fluid coagulant.

With the invention thereabove coagulation takes place from the inside of the polymer lining, which is preferably in the form of a tube. In addition the lining or tube is formed in one operation thus avoiding the problems that arise from products made with processes which build up the tube to the required wall thickness in a number of successive operations. The invention is particularly suitable for manufacturing small diameter tubes, for example, vascular prostheses with an internal diameter of less than 6 mm, which are often difficult to fabricate by known methods.

Preferably the body is a rod or of other tubular form. The cross-section of the hollow part of the body may be of any shape but will generally be circular.

A specific embodiment of the invention will now be described with reference to the accompanying drawings in which the Figures 1 to 6 show, diagrammatically, stages in the process of polymer tube formation.

Referring to the drawings, in the first stage of the process (Fig.1), a hollow rod 10 of the required length, preferably cylindrical and optionally manufactured from a transparent material, e.g. glass, is immersed below the meniscus of a reservoir containing a deaerated, viscous polymer solution 12. Said polymer solution may contain additives known to assist formation of a regular cellular or microporous structure. A viscous aqueous dispersion may also be used. Suction is applied to the open end 14 of the hollow rod (Fig.2) and the viscous polymer solution 12 is drawn up the tube as at 16. When the solution has partially filled the tube, to a height which depends on the desired length of the tube or other product, suction is stopped and the open end of the rod 14 is sealed with a temporary seal 18, so that the solution does not flow back down the tube under gravitational force (Fig.3). The hollow rod, partially filled with the polymer solution, is then withdrawn from the reservoir. Air or a gas (inert to the polymer solution) is then forced through the polymer solution by removing the temporary seal 18 and either applying suction to the end A of the hollow rod (Fig.4) or blowing air or an inert gas through the polymer from end 20 of the hollow tube (Fig.5). By either method, because of the viscous nature of the polymer solution, a coating 22 of polymer solution of controllable thickness is left adhering to the inner wall of the

hollow rod, with a central orifice of constant diameter (Fig.6). In the final step of the process, the porous polymer tube is formed by passing a fluid, which is capable of coagulating the polymer solution, through the central orifice thus created.

In one embodiment of the process, the coagulating fluid used in this last step is air or an inert gas. In this embodiment, it is necessary to dissolve the polymer in a mixture of a solvent and a proportion of a less volatile non-solvent insufficient to cause precipitation. When air or inert gas is passed down the central orifice of the polymer solution tube, the more volatile true solvent evaporates preferentially, thereby increasing the proportion of non-solvent in the polymer solution. At a critical concentration of solvent/non-solvent the polymer is precipitated out in the form of a highly porous tube. In this embodiment, therefore, the structure is developed by the so-called phase-separation process.

In another embodiment of the invention, the coagulating fluid is a liquid, which is a miscible with the original solvent. This miscible liquid may be a non-solvent for the polymer, or a mixture of solvent and non-solvent for the polymer. In this embodiment, passage of non-solvent down the central orifice of the polymer solution initiates the well known

solvent/non-solvent exchange reaction or coagulation process, which again leads to the development of a coherent but porous polymer structure. It is preferred that the coagulating liquid and the polymer solution have approximately similar densities, since this will minimise the tendency of the polymer solution to flow down or collapse into the centre of the hollow rod. An alternative technique is to rotate the hollow rod during the coagulation process so that the polymer solution adheres to the inner surface of the hollow rod by centrifugal forces.

By the invention the inner surface of the polymer tube is formed as an integral skin. Depending on the choice of polymer solution and coagulation medium, it is possible to produce an inner surface with chemical and physical properties that render it physiologically compatible with body fluids, e.g. blood. Moreover the invention can be used to produce very small diameter prostheses with properties closely matched to natural tissue.

If desired, however, the inner surface of the polymer tube may be further modified by coating it with a different porous or film forming polymer.

By correct choice of material for the hollow rod, the formed polymer tube can easily be removed therefrom after the micropore-forming process is complete.

Thirty grams of a polyester-based polyurethane of Shore hardness 78-85 were dissolved in seventy ml of dimethylformamide. Glass tubes of internal diameter approximately 6 mm and 3 mm were half-filled with the solution at ambient temperature and each one was then subjected to a sequence of operations as described above with reference to Figs.1 to 6. Air, drawn in by application of a vacuum as in Fig.4, was used to create the central orifice. Each tube was then lowered vertically into a bath of water and allowed to remain there for 18 hours, after which time the bath was flushed with running water until removal of dimethylformamide was complete. The polymer tubes so formed had internal diameters of 3.5 mm and 2 mm and hence wall thicknesses of approximately 1.25 mm and 0.5 mm respectively.

Cross-sectional examination clearly revealed that the tubes had a radially graded microporous structure, with the finest pores in the inner wall and the coarsest ones in the outer wall.

The invention is not confined to the above described embodiments. Many modifications can be made.

CLAIMS

1. A process for producing a cellular or microporous polymer product comprising drawing a polymer solution into a hollow body to form a lining of said polymer solution over at least a part of the inner surface of the body and contacting the said lining with a fluid coagulant.

2. A process as claimed in Claim 1, wherein the product is a tube.

3. A process as claimed in Claim 2, wherein the tube has an internal diameter of 6 mm or less.

4. A process as claimed in any preceding claim, wherein the polymer solution contains an additive to assist formation of regular cellular or microporous structure in the product.

5. A process as claimed in any preceding claim, wherein the fluid coagulant is a gas.

6. A process as claimed in any of Claims 1 to 4, wherein the fluid coagulant is a liquid.

7. A process as claimed in Claim 6, wherein the fluid coagulant is a non-solvent for the polymer.

8. A process as claimed in any preceding claim, wherein the polymer is an elastomer.

9. A process as claimed in Claim 8, wherein the polymer is a polyurethane.

10. A process as claimed in any preceding claim, wherein the hollow body is rotated to impose centrifugal force on the polymer solution in the hollow body and wherein the fluid coagulant is brought into contact with the polymer solution during said rotation.

11. A process as claimed in any preceding claim, wherein the surface of the product is coated with a different polymer.

12. A process for producing a cellular or microporous polymer substantially as described herein with reference to the accompanying drawing.

13. A cellular or microporous polymer product produced by the process as claimed in any preceding claim.

14. A cellular or microporous polymer product as claimed in Claim 13, in the form of a tube.